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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,867	07/03/2001	Banning G. Lary	SYN-053	4123
36822	7590	07/13/2004	EXAMINER	
GORDON & JACOBSON, P.C. 65 WOODS END ROAD STAMFORD, CT 06905			MENDEZ, MANUEL A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/898,867	Applicant(s) LARY ET AL.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-25 and 30-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8, 10-25, 30-34, and 31-50 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### Response to Amendment

The examiner of record has carefully reviewed arguments presented by applicant in the amendment dated February 20, 2004. Examiner thanks applicant for the clarification concerning **inflatable balloons and self-expanding elements**. In view of this clarification and further, the addition of a new method for the treatment of varicose veins, the examiner concludes that a restriction requirement is merited.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. **Claims 1-8 and 10-14**, drawn to an apparatus comprising a) **a first catheter tube** having a proximal end, a distal end, and a fluid lumen extending from its proximal end to its distal end; b) **an inflatable balloon** coupled to said distal end of said first catheter and in fluid communication with said fluid lumen; c) **a second catheter tube** having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end, said first catheter tube extending through said lumen of said second catheter tube; d) **a self-expanding element** coupled to said distal end of said second catheter tube, said first catheter tube extending through said self-expanding element; and e) **a third catheter tube** having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end, said second catheter tube extending through said lumen of said third catheter tube, wherein at least one of said second catheter tube and said third catheter tube is adapted to receive and deliver the intravascular drug

to the location of said self-expanding element., classified in class 604, subclass 96.01.

- II. Claims 15-19, drawn to an apparatus for delivering an intravascular drug, said apparatus comprising a) a catheter having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end; b) a drug reservoir having a drug outlet, said drug outlet being fluidly coupled to the proximal end of the lumen of the catheter, c) dispensing means coupled to said drug reservoir, said dispensing means being adapted to automatically dispense the drug from the reservoir into the lumen of the catheter as the catheter is moved through a blood vessel., classified in class 604, subclass 65.
- III. Claims 20-23, drawn to an apparatus for delivering an intravascular drug, said apparatus comprising a) a first catheter tube having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end; b) a self-expanding element coupled to said distal end of said first catheter tube; and a second catheter tube having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end, said first catheter tube extending through said lumen of said second catheter tube, wherein at least one of said first catheter tube and said self-expanding element includes pores, and said first catheter tube is adapted to receive and deliver the intravascular drug to said pores, classified in class 604, subclass 103.01.

- IV. Claims 24-25, drawn to an intravascular apparatus, comprising a) **a first catheter tube** having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end; b) **a self-expanding element** coupled to said distal end of said second catheter tube and having an abrasive outer surface; and c) **a second catheter tube** having a proximal end, a distal end, and a lumen extending from its proximal end to its distal end, said first catheter tube extending through said lumen of said second catheter tube, classified in class 604, subclass 104.
- V. Claims 30-34, drawn to **a method for delivering an intravascular drug to a blood vessel**, classified in class 604, subclass 508.
- VI. Claims 41-50, drawn to **a method for treating a varicose vein**, classified in class 604, subclass 500.

The inventions are distinct, each from the other because of the following reasons:

**Inventions I-IV** are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, inventions I-IV have separate utility in view of the structural and functional differences highlighted above. See MPEP § 806.05(d).

**Inventions V and VI** are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention V is a method for infusion of medicaments into a vessel. However, invention VI discloses a method clearly defined for the treatment of varicose

Art Unit: 3763

veins. Based on the differences mentioned above, these methods have different modes of operation, different functions, or different effects.

**Inventions I-IV and V-VI** are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, since the structural elements disclose in inventions I-IV are not disclosed in the method claims, it would be reasonable to conclude that methods V and VI as claimed can be practiced with another materially different product.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

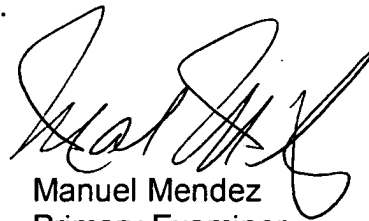
Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-308-2221. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Manuel Mendez', is positioned above the printed name and title.

Manuel Mendez  
Primary Examiner  
Art Unit 3763

MM